DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Florida District
555 Winderley Place, Suite 200
Maitland, Florida 32751

Telephone: 407-475-4700
FAX: 407-475-4769

VIA FEDERAL EXPRESS

WARNING LETTER

FLA-02-56

August 6, 2002

Mr. Terrell E. Yon, Jr.
President and Owner
TYA Pharmaceuticals
2930 Crescent Drive
Tallahassee, FL 32301

Dear Mr. Yon:

During an inspection of your drug repacking/labeling facility located at the above address on February 11-15, 2002, Investigators Paul Figarole and Leo Lagrotte documented deviations from the Current Good Manufacturing Practice (GMP) regulations (Title 21, Code of Federal Regulations (CFR), Parts 210 and 211). Failure to conform to GMP may cause products repacked and/or relabeled by your firm to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act). Investigators Figarole and Lagrotte found the following deviations from GMP:

1. Failure to establish written procedures for:
   (a.) the authority and responsibilities of the Quality Control unit;
   (b.) preparation of either Master Production and Control records or Standard Operating Procedures;
   (c.) the receipt and handling of components, containers, closures and package inserts/outserts;
   (d.) label control and review of labeled repacked product; and,
   (e.) handling of complaints and conducting appropriate investigations [21 CFR 211.180 et. seq.].

2. There is no stability data to support the expiration dates used, and repacked products from the same parent lot have different expiration dates [21 CFR 211.137].

3. Qualification of major equipment has not been documented, the equipment is not properly identified as to status, nor have written procedures been established for this [21 CFR 211.63, 105].

4. Process validations and equipment cleaning validations have not been done, nor have written procedures been established [21 CFR 211.110, 67].

5. There is no training program for employees in current Good Manufacturing Practice (GMPs) [21 CFR 211.25].

6. Recall Procedures are not followed or documented [21 CFR 211.150].

7. There is no complaint file, nor are appropriate investigations of complaints conducted [21 CFR 211.198].

The lack of adequate control over your repacking operation has led to numerous complaints (Medwatch reports) including: mislabeled drug products; lots with multiple expiration dates; poor blister pack seals; no package insert or the wrong insert; the lack of an Rx legend; and the wrong drug in the unit dose containers. These complaints generated two recalls by your firm in the past year, both of which were undocumented and inadequately handled.

On June 12-13, 2002, FDA Investigator Brant Schroeder visited your firm in response to a report of a product packaging mix-up, and was told that a number of corrections had been made regarding these deviations, and that other corrections were in progress; however, no documentation was provided to demonstrate any corrective action taken. Please provide all documentation supporting your assertion that corrections have been made or are in progress. Also, please provide the qualifications of the person you have hired as Quality Assurance Manager and describe where this individual is in your Table of Organization (who the person reports to, etc.).

The violations identified above are not intended to be an all-inclusive list of deficiencies at your facility. For additional information we refer you to the List of Observations left at your firm at the close of the February inspection. It is your responsibility to ensure that all products repacked and/or relabeled by your firm are in compliance with the Act and with the GMP regulations. Federal agencies are advised of the issuance of all warning letters about drugs so that they may take this information into account when considering the award of contracts. Additionally, pending export approval requests may not be approved until the above violations are corrected.

You should take prompt action to correct those deviations that remain and to provide documentation of corrections already taken, as requested above. Failure to promptly correct these deviations may result in regulatory action without further notice. Possible actions include seizure and/or injunction.

You should notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct all the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action has not been completed, please provide a timetable within which the corrections will be completed.

Your reply should be directed to the Food and Drug Administration, Attention: Martin E. Katz, Compliance Officer, 555 Winderley Place, Suite. 200, Maitland, Florida 32751, or you may call (407)475-4729.

Sincerely,

Emma R. Singleton
Director, Florida District